

2011 Military Health System Conference

New Emerging Technology Clinical Trials Participation – Policy and Processes

The Quadruple Aim: Working Together, Achieving Success

James N. Black, Col, USAF, MC

Jan 2011



TRICARE Management Activity

OVERVIEW



- Supplemental Health Care Program Coverage of Experimental Care
- Section 1631, FY08 National Defense Authorization Act (NDAA)
- Draft Recommendations and Procedures to Undersecretary of Defense (Personnel and Readiness)
- Contact Information

SHCP Coverage



- With limited exceptions for Phase II and III cancer trials, regulatory authority prohibits the use of Supplemental Health Care Program (SHCP) funds to pay for any medical care that has not been determined to be safe and effective
- Precludes coverage of experimental/emerging technology procedures or treatments and any follow-on care needed
 - Including medications

Section 1631, FY08 NDAA



- Under this provision the Secretary of Defense is authorized to provide any former members of the Armed Forces who were severely injured or ill while on active duty with the same medical and dental care as members on active duty
- Provided the care is not reasonably available through the Department of Veterans Affairs
- Authority expires December 31, 2012

(Draft) Recommendations and Procedures



- For Dr. Clifford Stanley, Under Secretary of Defense (Personnel and Readiness) signature
- Allow use of SHCP funds for emerging treatments/procedures
- Recommendations
 - Director, TMA will authorize use of SHCP funds to cover costs of care not covered by the clinical trial and any related medications or follow-on care
 - Seriously ill or injured ADSMs
 - Medically retired member who were seriously injured or ill while on active duty

(Draft) Recommendations and Procedures (cont)



- Be enrolled in the Federal Recovery Coordination Program
- Procedure/treatment performed at one of the medical institutions with which DoD has a research or partnership agreement
- For retired members, the care is not available from the Dept of VA

(Draft) Recommendations and Procedures (cont)



- Procedures
 - Service Medical Department identifies candidates
 - Service will prepare a package containing clinical history and proposed referral
 - Waiver Request
 - Include Informed Consent from institution
 - Services may have own internal process
 - Candidates will be fully informed of the risks and benefits of the care and provide consent

(Draft) Recommendations and Procedures (cont)



- Also informed of the nature, including limitations, of the medical benefits
 - Section 1631
- No pressure or influence shall be used to coerce a candidate to participate

(Draft) Recommendations and Procedures (cont)



- Director, TMA will establish a review board
 - Review all pertinent clinical details including scientific, ethical, or administrative considerations
 - Membership selected by Director, TMA and will include Service representation
 - Provide recommendation to Director, TMA
- Board deliberations and waiver decisions will be archived in a database
 - Long term tracking and reference capability

(Draft) Recommendations and Procedures (cont)



- For ADSM and retirees who have already undergone treatment
 - All other conditions met
 - Can enroll retroactively into FRCP if not already
 - Will have retroactive Director, TMA approval
 - Will still need to submit waiver package

Section 1631



- Section 1631 authority expires December 31, 2012
 - If not renewed or no change made to statutory or regulatory language then SHCP funds cannot be used
 - If ADSM receives treatment and retires or retiree receives treatment, SHCP funds cannot be used for continued care after above date

Contact Information



- TMA/Office of the Chief Medical Officer
Col Jim Black
 - james.black@tma.osd.mil
- CAPT Tom Doss
 - thomas.doss@tma.osd.mil
- Mr. Tim Stockdale
 - timothy.stockdale@tma.osd.mil

Contact Information



- TRICARE Regional Office Medical Directors
 - CAPT Chris Dorr (TRO-N)
 - christine.dorr@tma.osd.mil
 - Dr. Mike Montalvo (TRO-S)
 - miguel.montavo@tros.tma.osd.mil
 - COL Jim Baunchalk (TRO-W)
 - james.baunchalk@trow.tma.osd.mil

Contact Information



- Service Medical Directors
 - CAPT Susan Chittum
 - susan.chittum@navy.med.mil
 - COL Ted Cieslak
 - theodore.cieslak@us.army.mil
 - Col Keith Morita
 - keith.morita@pentagon.af.mil



QUESTIONS?